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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,668	02/13/2002	Ronald Vogels	25,290-B USA	8240

23307 7590 03/22/2004

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EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,668	VOGELS ET AL.	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-71 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, 44 and 45, drawn to a method for identifying a nucleic acid which induces lipid droplet formation, comprising transfecting an expression library with a candidate nucleic acid, incubating and then determining if a lipid droplet has been formed, classified in class 435, subclass 6.

II. Claims 26-43, drawn to a method of determining if a lipid droplet-inducing gene product is secreted, comprising expressing said gene product in transfected cells in the presence of non-transfected cells, and determining if the non-transfected cells produce lipid droplets, classified in class 435, subclass 29.

III. Claims 46, 47, 50-52, 70 and 71, drawn to a method of identifying a drug candidate for treating obesity, comprising contacting the test compound with the nucleic acid of SEQ ID NO:14 and determining binding affinity, classified in class 435, subclass 6.

IV. Claims 46, 47, 50-52, 70 and 71, drawn to a method of identifying a drug candidate for treating obesity, comprising contacting the test compound with the nucleic acid of SEQ ID NO:16, classified in class 435, subclass 6.

V. Claims 46, 47, 50-52, 70 and 71, drawn to a method of identifying a drug candidate for treating obesity, comprising contacting the test compound with the nucleic acid of SEQ ID NO:17 or 18, classified in class 435, subclass 6.

VI. Claims 48 and 49, drawn to a method of identifying a drug candidate for treating obesity, comprising contacting the test compound with a polypeptide encoded by the nucleic acid of SEQ ID NO:14, classified in class 435, subclass 29.

VII. Claims 48 and 49, drawn to a method of identifying a drug candidate for treating obesity, comprising contacting the test compound with a polypeptide encoded by the nucleic acid of SEQ ID NO:16, classified in class 435, subclass 29.

VIII. Claims 53-55, drawn to a method of identifying a drug candidate for treating one of the recited diseases, comprising contacting the test compound with the expression product of the nucleic acid of SEQ ID NO:14 or the antisense thereof, classified in class 514, subclass 44.

IX. Claims 53-55, drawn to a method of identifying a drug candidate for treating one of the recited diseases, comprising contacting the test compound with the expression product of the nucleic acid of SEQ ID NO:16 or the antisense thereof, classified in class 514, subclass 44.

X. Claims 56-58, drawn to a method of identifying a drug candidate for treating one of the recited diseases, comprising contacting the test compound with a cell containing an expression vector containing the nucleic acid of SEQ ID NO:14, classified in class 435, subclass 6.

XI. Claims 56-58, drawn to a method of identifying a drug candidate for treating one of the recited diseases, comprising contacting the test compound with a cell containing an expression vector containing the nucleic acid of SEQ ID NO:16, classified in class 435, subclass 6.

XII. Claims 56-58, drawn to a method of identifying a drug candidate for treating one of the recited diseases, comprising contacting the test compound with a cell

containing an expression vector containing the nucleic acid of SEQ ID NO:17 or 18, classified in class 435, subclass 6.

XIII. Claim 59, drawn to an antibody, classified in class 530, subclass 388.15.

XIV. Claim 60, drawn to a pharmaceutical composition comprising a polypeptide encoded by SEQ ID NO:14, classified in class 530, subclass 350.

XV. Claims 61, 62, 66 and 68, drawn to the nucleic acid of SEQ ID NO: 14 or a pharmaceutical composition comprising it, classified in class 514, subclass 44.

XVI. Claims 61, 62, 66 and 68, drawn to the nucleic acid of SEQ ID NO:16 or a pharmaceutical composition comprising it, classified in class 514, subclass 44.

XVII. Claims 61, 62, 66 and 68, drawn to the nucleic acid of SEQ ID NO:17 or 18 or a pharmaceutical composition comprising it, classified in class 514, subclass 44.

XVIII. Claim 63, drawn to a method of treating one of the recited diseases comprising administering a composition comprising a polypeptide encoded by SEQ ID NO:14, classified in class 514, subclass 2.

XIX. Claims 64 and 67, drawn to a method of treating one of the recited diseases comprising administering a vector comprising nucleic acid of SEQ ID NO:14, classified in class 514, subclass 44.

XX. Claims 64 and 67, drawn to a method of treating one of the recited diseases comprising administering a vector comprising nucleic acid of SEQ ID NO:16, classified in class 514, subclass 44.

XXI. Claims 64 and 67, drawn to a method of treating one of the recited diseases comprising administering a vector comprising nucleic acid of SEQ ID NO:17 or 18, classified in class 514, subclass 44.

XXII. Claims 65 and 69, drawn to a method of treating obesity comprising administering a vector comprising the nucleic acid of SEQ ID NO:14, classified in class 514, subclass 44.

XXIII. Claims 65 and 69, drawn to a method of treating obesity comprising administering a vector comprising the nucleic acid of SEQ ID NO:16, classified in class 514, subclass 44.

XXIV. Claims 65 and 69, drawn to a method of treating obesity comprising administering a vector comprising the nucleic acid of SEQ ID NO:17 or 18, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-XIII and XVIII-XXIV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods or different products or products and methods which are unrelated. Methods of I-XII all differ from the methods of XVIII-XXIV, as the former are screening methods and the latter are treatment methods, and are thus different in modes of operation, functions and outcomes or effects. I and II differ from III-XII, as the former screen for nucleic acid or test it, whereas the latter screen for drugs, and are

thus different in modes of operation, functions and outcomes or effects. I and II differ from each other in that I screens for a nucleic acid with lipid droplet formation function, whereas II screens for a different function of a nucleic acid already identified. III-XII differ in the disease upon which the screen is based (obesity versus the other recited diseases) and/or the compound used in the screen (one of the nucleic acids versus one of the polypeptides), and thus have different modes of operation and outcomes/effects. (Note that SEQ ID NOS: 17 and 18 are not separated in this restriction requirement, either for the nucleic acids or polypeptides.) XVIII-XXIV differ in the disease being treated (obesity versus the other recited diseases) and/or the compound used in the screen (one of the nucleic acids versus one of the polypeptides), and thus have different modes of operation and outcomes/effects.

Inventions XIII-XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally distinct chemical entities, i.e., an antibody, the polypeptide encoded by SQ ID NO:14, and the three nucleic acids, of SEQ ID NOS: 14, 16 and 17/18.

Inventions of Groups I and XV/XVI/XVII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acids of the product Groups could be made by chemical synthesis, and the nucleic acids identified by the method of making would include many other nucleic acids than those of Groups XV/XVI/XVII.

Inventions of Groups XV/XVI/XVII and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in a method of, e.g., identifying candidate drugs for treating obesity.

Inventions of Groups XV/XVI/XVII and III/IV/V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in a method of, e.g., testing for secretion of a polypeptide gene product.

Inventions of Groups XV/XVI/XVII and X/XI/XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in a method of, e.g., testing for secretion of a polypeptide gene product.

Inventions of Groups XV/XVI/XVII and XIX/XX/XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in a method of, e.g., identifying candidate drugs for treating obesity.

Inventions of Groups XV/XVI/XVII and XXII/XXIII/XXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in a method of, e.g., identifying candidate drugs for treating obesity.

Inventions of Groups XIV and VI/VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides may be used in a method of screening for candidate drugs for treating diseases other than obesity, or in a method of treatment of such diseases.

Inventions of Groups XIV and VII/IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides may be used in a method of screening for candidate drugs for treating obesity.

Inventions of Groups XIV and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides may be used in a method of screening for candidate drugs for treating obesity, or in a method of screening for candidate drugs for treating diseases other than obesity.

In all instances above, the nucleic acids of SEQ ID NOS:14, 16 and 17/18 represent chemically distinct entities not overlapping significantly in structure, as do the polypeptides encoded by SEQ ID NOS:14, 16 and 17/18.

Finally, where the distinction between any particular pair of restriction Groups is not discussed above, it is considered that the inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In each case the remaining comparison of the pair of different inventions is between a product and a method not making or using that product, which thus clearly lack common modes of operation, function and effect/outcome.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, the nucleic acids of SEQ ID NOS:14, 16 and 17/18, and also the polypeptides expressed by each, would require a separate sequence search, and as such, restriction between the sequences for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application, OTHER THAN OFFICIAL RESPONSES, may be submitted directly to the Examiner by facsimile transmission at (571) 273-0770. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). (703) 872-9306 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter fax number unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
March 19, 2004

JAMES KETTER
PRIMARY EXAMINER